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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,353	05/30/2001	Franco Cipriani	13706	9560

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EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/871,353	<b>Applicant(s)</b> CIPRIANI ET AL.	
	<b>Examiner</b> My-Chau T. Tran	<b>Art Unit</b> 1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5-7 and 19-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-7 and 19-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The finality of the rejection of the last Office action is withdrawn in view of the new ground(s) of rejection.

#### ***Status of Claims***

2. Applicant's amendment filed 11/20/2003 is acknowledged and entered. Claims 1-4 and 14-18 are canceled by the amendment. Claims 5 and 25 are amended by the amendment.
3. It is noted that in the "Listing of claims" applicant omitted the status of claims 8-13, however in the Office Action mailed on 7/22/2003 Claims 8-13 were canceled by the amendment filed on 5/15/2003. Thus Claims 8-13 is treated as cancelled claims.
4. Claims 5-7, and 19-26 are pending.

#### ***Allowable Subject Matter***

5. The indicated allowability of claims 5-7, 19-24 and 26 are withdrawn in view of the newly discovered reference(s) to Dørwald (US Patent 6,136,984), and Hollinshead (US Patent 5,942,387). Rejections based on the newly cited reference(s) follow.

#### ***New Rejections***

#### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 5-7, and 19-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a written description rejection)

The instant claims 5 and 19 briefly recite a compound of thiophene oligomers that comprise of NCS functional group.

The scope of this claim includes an infinite number of thiophene oligomers with a functional group of NCS wherein no distinguishing structural attributes are provided for the thiophene oligomers wherein the specification is directed to four types of thiophene oligomers with NCS (e.g. pg. 5). Compounds 1-4 shown on page 5 of the specification are as follows: 1) terthiophene oligomer with NCS attachment through a  $-\text{CH}_2\text{CH}_2-$  linker; 2) biphenyl thiophene with NCS attachment through a  $-\text{Si}(\text{CH}_3)_2\text{CH}_2-$  linker; 3) quadthiophene oligomer with NCS attachment through a  $-\text{Si}(\text{CH}_3)_2\text{CH}_2-$  linker; and 4) pentathiophene oligomer with NCS attachment through a  $-\text{Si}(\text{CH}_3)_2\text{CH}_2-$  linker. Although the thiophene oligomer core structure are well known, the linking of functional group NCS to the thiophene oligomer is not sufficiently taught in the specification. The instant claimed thiophene oligomer with NCS functional group could read on a broad genus. The specification disclosure does not sufficiently teach the broad genus of thiophene oligomers.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was

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in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

With the exception of linking the NCS to the thiophene construct by the linker such as -CH<sub>2</sub>CH<sub>2</sub>- and -Si(CH<sub>3</sub>)<sub>2</sub>CH<sub>2</sub>- disclosed by the specification (e.g. pg. 5), the skilled artisan cannot envision the broad genus of the claimed thiophene oligomers with NCS. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails

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to describe the common attributes or characteristics that identify all of the members of the genus or even a substantial portion thereof, and because the genus is enormous and highly variant, listing examples like compounds 1-4 on page 5 of the specification is insufficient to teach the entire genus. Consequently, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe this enormous genus. Thus, applicant was not in possession of the claimed genus.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 5-7, and 19-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to the attachment site of the NCS functional group to the thiophene oligomers. That is where on a single thiophene (e.g. carbon site 2-5 of the thiophene structure) or on which of the plurality thiophene such as a terthiophene is the NCS functional group can be attached for the attachment site would dictate the interaction of NCS with the biological molecule.

#### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 5 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Hollinshead (US Patent 5,942,387).

Hollinshead discloses several differently substituted thiophenes compounds and method of screening these thiophene compounds (col. 4, lines 27-49; col. 44, lines 36-50). One type of functional group attached to the thiophene compounds includes organic isothiocyanates (NCS) (claim 1-2). Therefore the thiophenes compounds of Hollinshead anticipate the presently claimed thiophenes.

12. Claims 5-6, 19-20, and 22-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Dørwald (US Patent 6,136,984).

Dørwald discloses several differently substituted thiophenes compounds and method of screening these thiophene compounds (col. 3, lines 8-19). One type of functional group attached

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to the thiophene compounds includes NCS wherein the attachment is through an alkyl group (col. 10, lines 37-41; col. 11, lines 21-34). These compounds are screened for its binding interaction with an enzyme (col. 12, line 66 to col. 13, line 9). Therefore the thiophenes compounds of Dørwald anticipated the claimed thiophene compound.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct  
February 6, 2004

  
PADMASHRI PONNALURI  
PRIMARY EXAMINER